Refine Search

Search Results -

Term	Documents
(1 AND 5).USPT,USOC,EPAB,JPAB,DWPI.	7
(L1 AND L5).USPT,USOC,EPAB,JPAB,DWPI.	7

Database:
US Pre-Grant Publication Full-Text Database
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Search: L6

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DATE: Tuesday, November 08, 2005 Printable Copy Create Case

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DB=USPT,USOC,EPAB,JPAB,DWPI; PLUR=YES; OP=ADJ			
L6	l1 and L5	7	L6
L5	L4 and hydrocolloid	207	L5
L4	L3 and coating	2716	L4
L3	ibuprofen	7967	L3
L2	L1 and fumaric acid	3	L2
L1	(hydrocolloid coating)	33	L1

END OF SEARCH HISTORY

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Search Results -

Term	Documents
COATING	1464201
COATINGS	311249
(3 AND COATING).USPT,USOC,EPAB,JPAB,DWPI.	2716
(L3 AND COATING).USPT,USOC,EPAB,JPAB,DWPI.	2716

Database: US Pre-Grant Publication Full-Text Database; US Patents Full-Text Database; US OCR Full-Text Database; EPO Abstracts Database; JPO Abstracts Database; Derwent World Patents Index; IBM Technical Disclosure Bulletins

Search: L4 and hydrocolloid

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Set Name side by side	Query	Hit Count	Set Name result set
DB=USPT,USOC,EPAB,JPAB,DWPI; PLUR=YES; OP=ADJ			
L4	L3 and coating	2716	L4
L3	ibuprofen	7967	L3
L2	L1 and fumaric acid	3	L2
L1	(hydrocolloid coating)	33	L1

END OF SEARCH HISTORY

L6: Entry 4 of 7 File: USPT Aug 29, 1995

DOCUMENT-IDENTIFIER: US 5445826 A
TITLE: Delivery system containing a gel-forming dietary fiber and a drug

Abstract Text (1):
A prolonged-release unit dosage formulation or pharmaceutical composition, preferably in tablet form, is described. The composition consists essentially of a gel-forming fiber, preferably hydrocolloid-coated, a biologically-absorbable drug or other active therapeutic agent which is also preferably hydrocolloid-coated, a mineral salt which releases a physiologically-acceptable gas upon ingestion, preferably carbon dioxide, e.g., a mineral carbonate or bicarbonate, and optionally an organic or phosphoric acid and a dextrose or like soluble sugar. The fiber-containing composition, when in the form of a tablet or other unit dosage form together with the drug or agent and the stated disintegrants, provides a unique, efficient and controllable prolonged-action drug-delivery system.

Brief Summary Text (5):
Various cellulose derivatives have been used to provide rapid disintegration of tablets, such as in U.S. Pat. No. 3,266,992, which describes the use of methylcellulose, sodium carboxymethylcellulose and hydroxyethylcellulose for such purpose. However, in contrast, hydroxypropylmethylcellulose in enteric coatings has been disclosed in U.S. Pat. No. 2,887,440 to prevent disintegration of a tablet core and delay release of the active ingredients.

Brief Summary Text (19):
"when a biological liquid begins to penetrate or wick into the prolonged-release unit dosage formulation, it dissolves the acid and mineral salt present therein, which react together to cause a rapid evolution of gas, e.g., carbon dioxide, which cannot be effected using either stomach acid alone or the mineral salt alone. This rapid evolution of gas breaks up the prolonged-release unit dosage form, e.g., tablet, granule, capsule, lozenge, or the like, before a surface layer of gel can form around the unit dosage form, especially a tablet, from the normal reaction of the gel-forming dietary fiber, which surface layer of gel would seal the unit dosage form off from further hydration and disintegration. As already stated, stomach acid alone is not sufficiently rapid acting and is furthermore outside of the unit dosage form, so that it is necessary to have both the physiologically-acceptable edible acid and the mineral salt which releases a physiologically-acceptable gas upon ingestion, inside the tablet, granule, capsule, lozenge, or the like, or dispersed throughout the tablet, granule, capsule, lozenge, or other unit dosage form, to increase the speed of hydration of the drug or other therapeutic agent contained in the unit dosage formulation. According to the invention, the gel produced by the gel-forming dietary fiber modulates the release of the drug, but does not prevent the drug from being biologically absorbed, inhibition of disintegration by formation of a gel coating around the unit dosage formulation by the gel-forming dietary fiber being prevented by the evolution of a physiologically-acceptable gas by virtue of the combined action of the acid and mineral salt within the unit dosage formulation itself upon contact with biological fluids, e.g., those of the gastrointestinal tract."

Brief Summary Text (26):
According to the present invention, which I consider to be an advancement in the

art and a further extension of the invention of my previous U.S. Pat. No. 5,096,714, I combine in a unit dosage form, e.g., tablet, the gel-forming fiber and the drug or other therapeutic agent, and an amount of a mineral salt which releases a physiologically-acceptable gas upon ingestion, e.g., a mineral carbonate or bicarbonate, and may include other normal pharmaceutical excipients. For certain results, I also include a pharmaceutically-acceptable organic acid or phosphoric acid. Additionally, for certain purposes, I may also include a pharmaceutically-acceptable soluble sugar. In addition, I may coat the gel-forming fiber and optionally the drug or other therapeutic agent with a film of hydrocolloid, which may be the same or different than the gel-forming fiber employed. In this manner, I am able to control the release rate of the drug or other therapeutic agent from the fiber matrix over a wide range, which has not heretofore been possible using the same or similar ingredients. For example, for a relatively quick-release tablet, or a tablet in which the bulk of the therapeutic agent is released relatively quickly while the remainder is released over an approximately eight (8) hour period, I may coat the gel-forming fiber particles with a film of the hydrocolloid and I may employ a smaller amount of mineral carbonate or bicarbonate. I may also employ an organic acid, such as citric acid, or phosphoric acid, to facilitate a more rapid release. In addition, a soluble sugar may be included. When I wish an even more rapid release, I may provide the hydrocolloid film coating on both of the gel-forming fiber particles and the drug or other therapeutic agent particles. I may also increase the amount of the mineral carbonate or bicarbonate and the amount of the organic or phosphoric acid present in the composition. When I wish to provide a shorter release time for the drug or other therapeutic agent, I may employ a hydrocolloid film coating on only the gel-forming fiber particles, or eliminate the hydrocolloid film entirely, and/or reduce the amount of mineral carbonate or bicarbonate employed and/or eliminate the organic acid or phosphoric acid completely. In this manner, I am able to provide either extremely long-acting or relatively short-acting pharmaceutical forms, and to control the release times and rates by controlling the amounts of the ingredients employed, as just representatively pointed out in the foregoing.

Brief Summary Text (31):
The present invention relates, inter alia, to the unexpected discovery that by precoating the gel-forming fiber or gum particles, and optionally but advantageously also the drug or other therapeutic agent particles, with a film of Sodium Carboxymethylcellulose (NACMC) or other hydrocolloid, including hydrocolloids such as, e.g., natural and modified gums, celluloses and modified celluloses, pectin, mucillages, modified starches, noncellulosic polysaccharides, algal polysaccharides, and mixtures thereof, particularly preferred hydrocolloids including carboxymethyl cellulose, methyl cellulose, karaya gum, acacia gum, sodium alginate, calcium alginate, hydroxypropylmethylcellulose, and mixtures thereof, and then tableting or granulating together with a mineral carbonate or bicarbonate to speed up hydration, the locking up or sealing from further hydration can be prevented and a smooth and controlled release of the active drug or agent can be achieved.

Brief Summary Text (33):
The release characteristics of the drug when a gel-forming fiber such as guar gum is used as an excipient can be depicted with a bell shaped curve. Good disintegration time is achieved from 1% to about 10%, but then starts going down above 10% until there is reduced disintegration and further hydration of the tablet because it begins to lock up. Tablets exhibiting this phenomenon have a film of gel on the surface with a powder core. The film of hydrated gel tends to seal the rest of the tablet from further hydration, or at least slows down the hydration considerably. This is true whether the drug is a water soluble drug, a slightly water-soluble drug, or a water insoluble drug. Coating of the fiber particles with a film of hydrocolloid keeps this from occurring when you do not wish it to do so. The optional coating of the drug or other therapeutic agent with a film of hydrocolloid also assists in a smooth and even release of the drug or agent over a

somewhat less extended period.

Brief Summary Text (34):
The apparent negative effect of gelation can thus be used to produce controlled-release of a drug, especially if, as in the following examples, one can obtain greater control of the hydration of the tablet, granule, etc., through coating the gel-forming fiber or gum particles. Mineral carbonate or bicarbonate, when present, increases the rate of drug release. The thus-designed tablet does not need to disintegrate to release the active therapeutic agent or drug, but can retain its shape and integrity as a tablet while gelling and swelling slightly. The drug is then slowly released from this gel matrix. Such a delivery system has a wide degree of control depending on whether one desires to deliver the majority of the drug in a few hours or over a longer period, e.g., 8 to 12 hours.

Brief Summary Text (43):
The Hydrocolloid

Brief Summary Text (44):
Hydrocolloids are organic polymers containing numerous hydrophilic groups such as --OH, --COOH, --SO.sub.4, --PO.sub.4, and --NH.sub.2. They may be vegetable gums such as tragacanth or animal protein such as gelatin. They are capable of uniting with water, and dissolve or swell in the presence of water.

Brief Summary Text (45):
Hydrocolloids useful in the present invention are water-soluble or water-swellable polymeric substances such as cellulosic polymers and gums. It is to be understood that any hydrocolloid may be employed according to the present invention. By way of example, suitable cellulosic polymers are cellulose ethers such as methyl cellulose, cellulose alkyl hydroxylates such as hydroxymethyl cellulose and hydroxyethyl cellulose, cellulose alkyl carboxylates such as carboxymethyl cellulose and carboxyethyl cellulose, and alkali metal salts of cellulose alkyl carboxylates such as sodium carboxymethyl cellulose and sodium carboxyethyl cellulose. Examples of suitable gums are gum acacia, guar gum, xanthan gum, gum tragacanth, seaweed hydrocolloids, such as carrageenans (sodium carrageenate and mixtures of sodium, potassium and calcium carrageenates), and water-soluble alginates (sodium or ammonium alginates).

Brief Summary Text (52):
A solid prolonged-release oral unit dosage composition for oral administration and ingestion in solid form, and intended to be swallowed as such, which consists essentially of a solid admixture of an effective dose of a biologically-absorbable therapeutic agent or drug, a gel-forming dietary fiber matrix, a mineral salt which releases a physiologically-acceptable gas upon ingestion, and a physiologically-acceptable acid, the combination of the fiber and mineral salt providing amounts thereof which effect prolonged but effective release of the drug or therapeutic agent upon oral ingestion and exposure of the solid composition to biological fluids, wherein the gel-forming dietary fiber comprises about 10% to about 85% by weight, the mineral salt comprises about 5% to about 75% by weight, the physiologically-acceptable acid comprises 0% to about 50% by weight, and the ratio of the weight of the gel-forming fiber to the weight of the drug or therapeutic agent is between about 1,000:0.5 and 1:1.5, the gel-forming dietary fiber particles being coated with a hydrocolloid film and the therapeutic agent or drug particles being optionally coated with a film of the same or a different hydrocolloid; such a

Brief Summary Text (61):
composition wherein the drug or therapeutic agent is in granular form, with a hydrocolloid film coating about the granules thereof; such a

Brief Summary Text (62):

composition wherein the hydrocolloid is a cellulose polymer, gum acacia, guar gum, xanthan gum, gum tragacanth, a carrageenan, or an alginate, or a combination of more than one thereof; such a

Brief Summary Text (63):
composition wherein the drug or therapeutic agent is in granular form, with a hydrocolloid coating about the granules thereof, and wherein both the gel-forming fiber and the drug or therapeutic agent are coated with a film of a hydrocolloid which is cellulose polymer, gum acacia, guar gum, xanthan gum, gum tragacanth, a carrageenan, or an alginate, or a combination of more than one thereof; such a

Brief Summary Text (64):
composition wherein at least the gel-forming dietary fiber is in the form of granules which are coated with a cellulose polymer coating, the composition optionally being compressed into a tablet form; such a

Brief Summary Text (70):
Moreover, a method for prolonging the release of a drug or therapeutic agent upon oral ingestion by a human being, comprising the step of orally administering to the said human being a prolonged-release unit dosage oral composition in solid form which consists essentially of a solid admixture of an effective dose of a biologically-absorbable therapeutic agent or drug, a gel-forming dietary fiber matrix, a mineral salt which releases a physiologically-acceptable gas upon ingestion, and a physiologically-acceptable acid, the combination of the fiber and mineral salt providing amounts thereof which effect prolonged but effective release of the drug or therapeutic agent upon oral ingestion and exposure of the solid composition to biological fluids, wherein the gel-forming dietary fiber comprises about 10% to about 85% by weight, the mineral salt comprises about 5% to about 75% by weight, the physiologically-acceptable acid comprises 0% to about 50% by weight, and the ratio of the weight of the gel-forming fiber to the weight of the drug or therapeutic agent is between about 1,000:0.5 and 1:1.5, the gel-forming dietary fiber particles being coated with a hydrocolloid film and the therapeutic agent or drug particles being optionally coated with a film of the same or a different hydrocolloid; such a

Brief Summary Text (79):
method wherein the drug or therapeutic agent is in granular form, with a hydrocolloid film coating about the granules thereof; such a

Brief Summary Text (80):
method wherein the hydrocolloid is a cellulose polymer, gum acacia, guar gum, xanthan gum, gum tragacanth, a carrageenan, or an alginate, or a combination of more than one thereof; such a

Brief Summary Text (81):
method wherein the drug or therapeutic agent is in granular form, with a hydrocolloid coating about the granules thereof, and wherein both the gel-forming fiber and the drug or therapeutic agent are coated with a film of a hydrocolloid which is cellulose polymer, gum acacia, guar gum, xanthan gum, gum tragacanth, a carrageenan, or an alginate, or a combination of more than one thereof; such a

Brief Summary Text (82):
method wherein the gel-forming dietary fiber is in the form of granules which are coated with a cellulose polymer coating, the composition optionally being compressed into a tablet form; such a

Brief Summary Text (92):
composition wherein at least the peptide or protein is coated with a protective hydrocolloid coating; such a

Brief Summary Text (94):
composition wherein gel-forming dietary fiber particles are coated with a hydrocolloid and optionally compressed into the form of a tablet.

Brief Summary Text (97):
method wherein gel-forming dietary fiber particles are coated with a hydrocolloid film and optionally compressed into the form of a tablet; as well as such a

Brief Summary Text (99):
Finally, a solid prolonged-release oral unit dosage composition for oral administration and ingestion in solid form, and intended to be swallowed as such, which consists essentially of a solid admixture of an effective dose of a biologically-absorbable therapeutic agent or drug, a gel-forming dietary fiber matrix, a mineral salt which releases a physiologically-acceptable gas upon ingestion, and a physiologically-acceptable acid, the combination of the fiber and mineral salt providing amounts thereof which effect prolonged but effective release of the drug or therapeutic agent upon oral ingestion and exposure of the solid composition to biological fluids, wherein the gel-forming dietary fiber comprises about 10% to about 85% by weight, the mineral salt comprises about 5% to about 75% by weight, the physiologically-acceptable acid comprises 0% to about 50% by weight, and the ratio of the weight of the gel-forming fiber to the weight of the drug or therapeutic agent is between about 1,000:0.5 and 1:1.5, the gel-forming dietary fiber particles being optionally coated with a hydrocolloid film and the therapeutic agent or drug particles being optionally coated with a film of the same or a different hydrocolloid; such a

Brief Summary Text (108):
composition wherein at least the gel-forming dietary fiber is in the form of granules which are coated with a hydrocolloid film coating, the composition optionally being compressed into a tablet form; and such a

Brief Summary Text (109):
composition wherein the drug or therapeutic agent is in granular form, the granules being coated with a hydrocolloid film, the composition optionally being compressed into a tablet form.

Detailed Description Text (13):
Moreover, the composition of the foregoing Example, wherein the gel-forming fiber is precoated with hydrocolloid, as in Example 1, is found to be superior to the same composition wherein neither the gel-forming fiber nor the therapeutic agent are precoated, but the same composition wherein both the gel-forming fiber and the therapeutic agent are precoated is highly advantageous especially when a quick-controlled release tablet, such as illustrated by Example 1, is desired.

Detailed Description Text (14):
In both Examples, photographs show that the tablet appearance after 8 hours is a slightly enlarged, gelled version of its original shape, indicating that the drug has been released out of a matrix of the coated gel-forming guar gum without complete disintegration or dispersion of the fiber being necessary. The products of both Example 1 and Example 2 comprise a fiber-matrix which retains its integrity and passes through the intestinal tract and is eliminated through the bowels. Such expendable gel-fiber controlled-release tablet can be designed to release the active drug contained therein either quickly or slowly. This provides the ability to release a drug in the small intestine, which should be about 5 hours after ingestion. The gel-fiber matrix also exhibits viscosity which slows its passage through the gastrointestinal tract, allowing for smoother release of a drug as well as for the gel to act as an excellent antacid-like protective agent, buffering the contact of the drug with the intestinal lining. It is precisely this property which allows for improved delivery of certain analgesics such as Aspirin and Ibuprofen and other nonsteroidal anti-inflammatory drugs (NSAIDs) as given in the examples

which follow:

Detailed Description Text (80):
Other cellulose coatings or other hydrocolloid coatings, including hydrocolloids such as, e.g., natural and modified gums, celluloses and modified celluloses, pectin, mucillages, modified starches, noncellulosic polysaccharides, algal polysaccharides and mixtures thereof, may replace those used in the foregoing.

Detailed Description Text (94):
Niacin Tablet-Coating Variations

Detailed Description Text (97):
The same formula can be duplicated but with the coating on the guar gum being gelatin at a 5% level (225 bloom gelatin).

Detailed Description Text (108):
a. Antipyretics, and nonsteroidal anti-inflammatory drugs (NSAIDs), and analgesics such as acetaminophen, aspirin and ibuprofen

Detailed Description Text (119):
Niacin, Vitamin B-12, Potassium Chloride, Vitamin C, Aspirin, Caffeine, Phenylpropanolamine hydrochloride, Ibuprofen, Pseudoephedrine, Nitroglycerin, and Gemfibrozil.

Detailed Description Text (120):
The active ingredient can be any type of medication which acts systemically and which can be administered orally to transmit the active therapeutic agent into the gastrointestinal tract and into the bloodstream in therapeutically-effective levels without early excessive peak concentrations, without being inactivated by physiological fluids, and without passing unchanged through the body of the patient or subject by being excreted unabsorbed. Alternatively, the active ingredient can be any type of medication which acts through the buccal tissues of the mouth to transmit the active ingredient directly into the bloodstream, thus bypassing both any possible first pass liver metabolism and/or the gastric and intestinal fluids, which often have an adverse inactivating or destructive action on the active ingredient unless it is specially protected against such fluids as by means of an enteric coating or the like. The active ingredient can also be a type of medication which can be transmitted into the blood circulation through the rectal tissues.

Detailed Description Text (122):
It is therefore seen that the present invention provides a unique prolonged-release dosage formulation, especially a tablet, consisting of the following as essential ingredients: an effective dose of a biologically-absorbable drug or other therapeutic agent, preferably coated with a hydrocolloid, a gel-forming fiber, such as guar gum, preferably coated with a hydrocolloid, a mineral salt which releases a physiologically-acceptable gas upon ingestion, preferably a mineral carbonate or bicarbonate, optionally a physiologically-acceptable acid, especially a food-grade organic acid or phosphoric acid, and optionally and advantageously dextrose or another soluble sugar as a further disintegrant, and a method of controllably prolonging the release of a drug or other active therapeutic agent upon administration to a living animal body, e.g., a human being or other animal, by employment of such a prolonged-release pharmaceutical, therapeutic, or dietary composition, all having the unpredictable and highly advantageous characteristics and effects as more fully set forth in the foregoing.

Detailed Description Paragraph Table (1):

	Each tablet contains:	Wt. %
Guar Gum (granulated)*	450 mg.	37.19
Niacin (granulated)*	212 mg.	17.769
Calcium Carbonate	200 mg.	14.463
Microcrystalline Cellulose (M.C.C.)	150 mg.	12.397
Citric Acid	60 mg.	4.958
Dextrose	50 mg.	4.545

Oat Fiber 50 mg. 4.132 Magnesium Oxide 25 mg. 2.066 Silicon Dioxide 15 mg. 1.240 Magnesium Stearate 15 mg. 1.240 _____ *The Niacin particles are coated in a fluid bed granulator and are 95% Niacin comprising a first coating or film of 3% NACMC (Sodium Carboxymethylcellulose) followed by a subsequent coating or film of 2% Surelease, a polymeric dispersion of ethylcellulose (Colorcon 7060). A guar gum granulate is made comprising Aqualon Supercol G3 Guar Gum and sprayed with NACMC (Sodium Carboxymethylcellulose, 1.8%, at 7.5% solids i solution). The NACMC coating or film in both applications is Aqualon 7L2P).

Detailed Description Paragraph Table (5):

_____ Coated Guar Gum* 450 mg. Coated Ibuprofen* 212 mg. Calcium Carbonate 200 mg. Microcrystalline Cellulose 150 mg. Dextrose 50 mg. Silicon Dioxide 15 mg. Magnesium Stearate 15 mg.

_____ *The Ibuprofen is coated in a fluid bed granulator and is 95% Ibuprofen comprising a first coating of 3% NACMC (Sodium Carboxymethylcellulose) followed by a subsequent coating of 2% Surelease, a polymeric dispersion of ethylcellulose (Colorcon 7060). A guar gum granulate is made comprisin Aqualon Supercol G3 Guar Gum sprayed with NACMC (Sodium Carboxymethylcellulose, 1.8%, at 7.5% solids in solution). The NACMC coating in both applications is Aqualon 7L2P.

Detailed Description Paragraph Table (19):

_____ Maximum Ratio Example (1:2) (large amount of drug) Each tablet contains: _____ Guar Gum (coated) 350 mg Ibuprofen 700 mg Calcium Carbonate 50 mg Citric Acid (optional) 50 mg Dextrose (optional) 50 mg MCC 25 mg _____

Detailed Description Paragraph Table (21):

_____ Guar Gum (coated)* 200 mg. Sodium Carboxymethylcellulose 50 mg. (crosslinked) Calcium Carbonate 50 mg. Lactose 50 mg. DiCalcium Phosphate 50 mg. Silicon Dioxide 10 mg. Magnesium Stearate 5 mg. Chromium Chloride or 100 mcg. Chromium Polynicotinate _____ *The guar gum is precoated with an ethylcellulose coating at 1.5% in a fluidbed granulator and is therefore 98.5% guar gum.

CLAIMS:

1. A solid prolonged release oral unit dosage composition for oral administration and ingestion in solid form, and intended to be swallowed as such, which consists essentially of a solid admixture of an effective dose of particles of a biologically-absorbable therapeutic agent or drug, gel-forming dietary matrix particles, a mineral salt of carbonate or bicarbonate which releases a physiologically-acceptable gas upon ingestion, and a physiologically-acceptable acid, the combination of the fiber and mineral salt providing amounts thereof which effect prolonged but effective release of the drug or therapeutic agent upon oral ingestion and exposure of the solid composition to biological fluids, wherein the gel-forming dietary fiber comprises about 35% to about 50% by weight, the mineral salt comprises about 5% to about 75% by weight, the physiologically-acceptable acid comprises 0% to about 50% by weight, and the ratio of the weight of the gel-forming fiber to the weight of the drug or therapeutic agent is between about 1,000:0.5 and 1:1.5, the gel-forming dietary fiber particles being coated with a hydrocolloid film and the therapeutic agent or drug particles being optionally coated with a film of the same or a different hydrocolloid.

2. A method for prolonging the release of a drug or therapeutic agent upon oral ingestion by a human being, comprising the step of orally administering to the said human being a prolonged release unit dosage oral composition which consists essentially of a solid admixture of an effective dose of particles of a biologically-absorbable therapeutic agent or drug, gel-forming dietary matrix

particles, a mineral salt of carbonate or bicarbonate which releases a physiologically-acceptable gas upon ingestion, and a physiologically-acceptable acid, the combination of the fiber and mineral salt providing amounts thereof which effect prolonged but effective release of the drug or therapeutic agent upon oral ingestion and exposure of the solid composition to biological fluids, wherein the gel-forming dietary fiber comprises about 35% to about 50% by weight, the mineral salt comprises about 5% to about 75% by weight, the physiologically-acceptable acid comprises 0% to about 50% by weight, and the ratio of the weight of the gel-forming fiber to the weight of the drug or therapeutic agent is between about 1,000:0.5 and 1:1.5, the gel-forming dietary fiber particles being coated with a hydrocolloid film and the therapeutic agent or drug particles being optionally coated with a film of the same or a different hydrocolloid.

3. A solid prolonged release oral unit dosage composition for oral administration and ingestion in solid form, and intended to be swallowed as such, which consists essentially of a solid admixture of an effective dose of particles of a biologically-absorbable therapeutic agent or drug, gel-forming dietary matrix particles, a mineral salt of carbonate or bicarbonate which releases a physiologically-acceptable gas upon ingestion, and a physiologically-acceptable acid, the combination of the fiber and mineral salt providing amounts thereof which effect prolonged but effective release of the drug or therapeutic agent upon oral ingestion and exposure of the solid composition to biological fluids, wherein the gel-forming dietary fiber comprises about 35% to about 50% by weight, the mineral salt comprises about 5% to about 75% by weight, the physiologically-acceptable acid comprises 0% to about 50% by weight, and the ratio of the weight of the gel-forming fiber to the weight of the drug or therapeutic agent is between about 1,000:0.5 and 1:1.5, the gel-forming dietary fiber particles being optionally coated with a hydrocolloid film and the therapeutic agent or drug particles being optionally coated with a film of the same or a different hydrocolloid.

4. A solid prolonged-release oral unit dosage composition for oral administration and ingestion in solid form, and intended to be swallowed as such, which consists essentially of a solid admixture of an effective dose of particles of a biologically-absorbable therapeutic agent or drug, gel-forming dietary fiber matrix, a mineral salt carbonate or bicarbonate which releases a physiologically-acceptable gas upon ingestion, and a physiologically-acceptable acid, the combination of the fiber and mineral salt providing amounts thereof which effect prolonged but effective release of the drug or therapeutic agent upon oral ingestion and exposure of the solid composition to biological fluids, wherein the gel-forming dietary fiber comprises about 30 to about 40% by weight, the mineral salt comprises about 5% to about 75% by weight, the physiologically-acceptable acid comprises 0% to about 50% by weight, and the ratio of the weight of the gel-forming fiber to the weight of the drug or therapeutic agent is between about 1,000:0.5 and 1:1.5, the gel-forming dietary fiber particles being coated with a hydrocolloid film and the therapeutic agent or drug particles being optionally coated with a film of the same or a different hydrocolloid.

5. A solid prolonged-release oral unit dosage composition for oral administration and ingestion in solid form, and intended to be swallowed as such, which consists essentially of a solid admixture of an effective dose of particles of a biologically-absorbable therapeutic agent or drug, gel-forming dietary fiber matrix, a mineral salt carbonate or bicarbonate which releases a physiologically-acceptable gas upon ingestion, and a physiologically-acceptable acid, the combination of the fiber and mineral salt providing amounts thereof which effect prolonged but effective release of the drug or therapeutic agent upon oral ingestion and exposure of the solid composition to biological fluids, wherein the gel-forming dietary fiber comprises about 10% to about 85% by weight, the mineral salt comprises about 5% to about 75% by weight, the physiologically-acceptable acid comprises 0% to about 50% by weight, and the ratio of the weight of the gel-forming fiber to the weight of the drug or therapeutic agent is between about 1,000:0.5 and

1:1.5, the gel-forming dietary fiber particles being coated with a cellulose polymer coating and the therapeutic agent or drug particles being optionally coated with a film of the same or a different cellulose polymer coating.

7. A method for prolonging the release of a drug or therapeutic agent upon oral ingestion by a human being, comprising the step of orally administering to the said human being a prolonged-release unit dosage oral composition in solid form which consists essentially of a solid admixture of an effective dose of particles of a biologically-absorbable therapeutic agent or drug, a gel-forming dietary fiber matrix particle, a mineral salt carbonate or bicarbonate which releases a physiologically-acceptable gas upon ingestion, and a physiologically-acceptable acid, the combination of the fiber and mineral salt providing amounts thereof which effect prolonged but effective release of the drug or therapeutic agent upon oral ingestion and exposure of the solid composition to biological fluids, where the gel-forming dietary fiber comprises about 30% to about 40% by weight, the mineral salt comprises about 5% to about 75% by weight, the mineral salt comprises about 5% to about 75% by weight, the physiologically-acceptable acid comprises 0% to about 50% by weight, and the ratio of the weight of the gel-forming fiber to the weight of the drug or therapeutic agent is between about 1,000:0.5 and 1:1.5, the gel-forming dietary fiber particles being coated with a hydrocolloid film and the therapeutic agent or drug particles being optionally coated with a film of the same or a different hydrocolloid.

8. A method for prolonging the release of a drug or therapeutic agent upon oral ingestion by a human being, comprising the step of orally administering to the said human being a prolonged-release unit dosage oral composition in solid form which consists essentially of a solid admixture of an effective dose of particles of a biologically-absorbable therapeutic agent or drug, a gel-forming dietary fiber matrix particle, a mineral salt carbonate or bicarbonate which releases a physiologically-acceptable gas upon ingestion, and a physiologically-acceptable acid, the combination of the fiber and mineral salt providing amounts thereof which effect prolonged but effective release of the drug or therapeutic agent upon oral ingestion and exposure of the solid composition to biological fluids, where the gel-forming dietary fiber comprises about 10% to about 85% by weight, the mineral salt comprises about 5% to about 75% by weight, the mineral salt comprises about 5% to about 75% by weight, the physiologically-acceptable acid comprises 0% to about 50% by weight, and the ratio of the weight of the gel-forming fiber to the weight of the drug or therapeutic agent is between about 1,000:0.5 and 1:1.5, the gel-forming dietary fiber particles being coated with a cellulose polymer coating and the therapeutic agent or drug particles being optionally coated with a film of the same or a different cellulose polymer coating.

10. A solid prolonged-release oral unit dosage composition for oral administration and ingestion in solid form, and intended to be swallowed as such, such consists essentially of a solid admixture of an effective dose of a biologically absorbable therapeutic agent or drug, a gel-forming dietary fiber matrix, a mineral salt which releases a physiologically-acceptable gas upon ingestion, and a physiologically-acceptable acid, the combination of the fiber and mineral salt providing amounts thereof which effect prolonged but effective release of the drug or therapeutic agent upon oral ingestion and exposure of the solid composition to biological fluids, wherein the gel-forming dietary fiber comprises about 30% to about 40% by weight, the mineral salt comprises about 5% to about 75% by weight, the physiologically-acceptable acid comprises 0% to about 50% by weight, and the ratio of the weight of the gel-forming fiber to the weight of the drug or therapeutic agent is between about 1,000:0.5 and 1:1.5, the gel-forming dietary fiber particles being optionally coated with a hydrocolloid film and the therapeutic agent or drug particles being optionally coated with a film of the same or a different hydrocolloid.

L6: Entry 5 of 7 File: USPT Jun 2, 1992

+ 4888177

DOCUMENT-IDENTIFIER: US 5118510 A
TITLE: Niacin drink mix formulation

Brief Summary Text (14):
Applegren (U.S. Pat. No. 4,754,027) describes coating fine particles of guar gum with water:solvent and film-forming fatty acids, film-forming polymers, and ethyl cellulose. Examples of solvents are ethanol, lower ketones such as acetone, benzene, xylene, and toluene. An example is the use of a polymer of dimethylaminoethyl-methacrylate for the film-forming agent and acetone:isopropanol (40:60) as solvent. Among the many drawbacks of his contribution are the use of pollution-causing substances which require special pollution-control devices and subject the manufacture to regulatory control; the expense of the film-forming agents and solvents, making this product very expensive; and failure to provide for a further dispersion of the fine guar particles within the granules, so that, after his film dissolves, the guar still has an impenetrable film of guar gel around the nucleus. In addition, his particle size and the texture of his particles create a gritty texture and an objectionable mouthfeel to the product and his particles have a tendency to sink to the bottom when mixed in a liquid, quite in contrast to the granules of the present invention, which do not have these shortcomings.

Brief Summary Text (18):
U.S. Pat. Nos. 4,790,991, 4,747,881, and 4,818,539 describe coating dietary fibers and drugs with a preswelled hydrocolloid, wherein the substrate (drug or fiber) and the hydrocolloid are not the identical material, and wherein the substrate contains cholestyramine. The hydrocolloids are selected from the group consisting of natural and modified gums, cellulose, modified celluloses, pectin, mucillages, modified starches, etc. U.S. Pat. No. 4,747,881 in particular describes coating locust bean gum with carboxymethylcellulose (Example 1). There is no mention of the use of a mineral carbonate or bicarbonate or an edible acid or of gelatin or a caseinate as coating agents. The particles created tend to form small spheres which have a gel coating around their circumference. The hydrocolloid coating slows down the gelation of the aggregate, but each individual particle does not fully disperse or hydrate when the hydrocolloid layer dissolves and the gastric fluid comes in contact with the core material (substrate). Furthermore, the hydrocolloid is always different than the substrate or core material.

Brief Summary Text (21):
The inhibition is reversed when the mixture is consumed and reaches the acid environment of the stomach where there is a pH change. Other protein hydrolysates and carbohydrate derivatives are also mentioned as inhibitors, because they are susceptible to pH change. The formulation also requires an alkalinizer to adjust the pH and insure inhibition of gelation. Nowhere in this patent is mentioned the coating of guar or other gel-forming fibers with gelatin or other protein or with any other substance.

Brief Summary Text (22):
GB 2021948 discloses the coating of gums such as guar gum or locust bean gum with a layer of protein such as soya flour, gluten, or casein having a greater tendency to absorb water than the gum. The gum and the coating substance are mixed in preferably equal amounts with water to produce a dough which is dried and crushed.

The resulting composition gels slowly when mixed with water. There is no mention of coating a mixture or granulate of a gel-forming dietary fiber, mineral carbonate or bicarbonate, and an edible acid, with or without a drug, with a protein such as gelatin or sodium caseinate or the like.

Brief Summary Text (28):
A readily-dispersible physiologically-effective fiber drink mix comprising granules consisting essentially of a blend of a mineral salt which releases a physiologically-acceptable gas upon ingestion, a physiologically-acceptable edible acid, and a gel-forming dietary fiber, said granules being coated with a gel-forming dietary fiber, starch, or protein coating, such a

Brief Summary Text (32):
drink mix wherein said gel-forming dietary fiber coating is also guar gum, such a

Brief Summary Text (37):
drink mix wherein said coating is a guar-gum coating, such a

Brief Summary Text (41):
drink mix wherein the coating on the granules comprises about 2% to about 25% by weight of the composition, such a

Brief Summary Text (42):
drink mix wherein the coating on the granules comprises about 5% to about 10% by weight of the composition, such a

Brief Summary Text (45):
drink mix wherein the gel-forming dietary fiber comprises about 25% to about 98% by weight of the composition, the physiologically-acceptable acid comprises about 0.5% to about 10% by weight of the composition, the mineral salt comprises about 1% to about 30% by weight of the composition, and the coating comprises about 2% to about 25% by weight of the composition, such a

Brief Summary Text (46):
drink mix wherein the coating comprises about 5% to about 10% by weight of the composition, such a

Brief Summary Text (47):
drink mix wherein the orally-ingestible pharmaceutically-active compound is present in granular form, with a cellulose coating about the granules thereof, such a

Brief Summary Text (48):
drink mix wherein the niacin is present in granular form, with a cellulose coating about the granules thereof, such a

Brief Summary Text (49):
drink mix wherein the coating is a combination of a carboxymethyl cellulose coating and an ethyl cellulose coating, such a

Brief Summary Text (50):
drink mix wherein the coating is a combination of a carboxymethyl cellulose coating and an ethyl cellulose coating, such a

Brief Summary Text (61):
said granules being coated externally with a coating selected from the group consisting of a gel-forming fiber, an animal or vegetable protein, and a starch, said coating being present in amount of about 2% to about 25% by weight of the composition, such a

Brief Summary Text (62):

composition wherein the external coating is a gel-forming fiber which is the same as the fiber present internally of the granules, such a

Brief Summary Text (63):
composition wherein the coating is present in amount of about 5% to about 10% by weight of the composition, such a

Brief Summary Text (70):
method wherein said gel-forming dietary fiber coating is also guar gum, such a

Brief Summary Text (75):
method wherein said coating is a guar-gum coating, such a

Brief Summary Text (79):
method wherein the coating on the granules comprises about 2% to about 25% by weight of the composition, such a

Brief Summary Text (80):
method wherein the coating on the granules comprises about 5% to about 10% by weight of the composition, such a

Brief Summary Text (83):
method wherein the gel-forming dietary fiber comprises about 25% to about 98% by weight of the composition, the physiologically-acceptable acid comprises about 0.5% to about 10% by weight of the composition, the mineral salt comprises about 1% to about 30% by weight of the composition, and the coating comprises about 2% to about 25% by weight of the composition, such a

Brief Summary Text (84):
method wherein the coating comprises about 5% to about 10% by weight of the composition, such a

Brief Summary Text (85):
method wherein the orally-ingestible pharmaceutically-active compound is present in granular form, with a cellulose coating about the granules thereof, such a

Brief Summary Text (86):
method wherein the niacin is present in granular form, with a cellulose coating about the granules thereof, such a

Brief Summary Text (87):
method wherein the coating is a combination of a carboxymethyl cellulose coating and an ethyl cellulose coating, such a

Brief Summary Text (88):
method wherein the coating is a combination of a carboxymethyl cellulose coating and an ethyl cellulose coating, such a

Brief Summary Text (99):
said granules being coated externally with a coating selected from the group consisting of a gel-forming fiber, an animal or vegetable protein, and a starch, said coating being present in amount of about 2% to about 25% by weight of the composition, such a

Brief Summary Text (100):
method wherein the external coating is a gel-forming fiber which is the same as the fiber present internally of the granules, such a

Brief Summary Text (101):
method wherein the coating is present in amount of about 5% to about 10% by weight

of the composition, such a

Brief Summary Text (125):
The Coating

Brief Summary Text (126):
The gel-forming fiber, protein, or starch coating agents employed according to the present invention may be selected from among any of the following gel-forming dietary fibers previously enumerated, gelatin, casein, soy, whey, egg, and any of various starches and modified starches.

Brief Summary Text (130):
According to the invention, the range for the gel-forming dietary fiber in the drink-mix granules is about 25% to 98% by weight of the composition, the range of physiologically-acceptable edible acid is about 0.5% to about 10% by weight of the composition, the range for the mineral salt is about 1% to about 30% by weight of the composition, and the weight of the gel-forming fiber, animal or vegetable protein, or starch coating on the particles is about 2% to about 25% by weight of the composition, preferably about 5% to 10% by weight of the finished product. When a drug is present in the granules of the powdered drink mix, it may conveniently be present in an amount of about 1% to about 50% by weight of the finished product. The gel-forming fiber, when employed as coating, is preferably the same fiber as employed as an essential part of the matrix of the granules themselves.

Brief Summary Text (132):
It has now been discovered that readily-dispersible drink mix granules which can be mixed in water or other liquid and orally ingested and which may optionally contain a drug, vitamin, dietary food supplement, or other active therapeutic agent, and which provide a unique, readily-dispersible, and advantageous drink-mix delivery system, can be provided which consist essentially of a gel-forming fiber, especially guar gum, a physiologically-acceptable edible acid, and a mineral salt which releases a physiologically-acceptable gas upon ingestion, the individual particles being coated with an outer coating consisting essentially of a gel-forming fiber, an animal or vegetable protein, or a starch. When mixed in water or other orally-ingestible liquid, the powdered drink mix is readily dispersed and, upon ingestion, the outer coating of the particles is weakened or removed by the action of the acid of the gastrointestinal tract, which activates the interior of the individual granules, which dissolves slowly, with the internally-contained acid and mineral salt cooperating to mechanically disperse the fiber in a slow and prolonged manner as it hydrates, the gas released by the mineral salt and organic or other acid assisting in the slow disintegration of the granules while the granules are in the gastrointestinal tract, the gas penetrating and modulating the film of the gel produced from the gel-forming dietary fiber contained within the individual granules and thus assisting in the proper disintegration of the granules and the proper dissolution of all of the drug or other therapeutic agent when present in the formulation of the invention. In addition to the external coating on the individual particles, it is the combined action of the physiologically-acceptable edible acid and the mineral salt which releases the physiologically-acceptable gas upon ingestion which cooperatively provides the advantageous characteristics to the formulations of the present invention. The present invention preferably employs a mineral carbonate or bicarbonate, and a physiologically-acceptable food-grade organic acid or phosphoric acid which, as previously set forth, are essential for the proper disintegration of the individual particles and dissolution of the granules within the intestinal tract.

Brief Summary Text (135):
a. Antipyretics and analgesics such as acetaminophen, aspirin and ibuprofen

Brief Summary Text (145):
Niacin, Vitamin B-12, Potassium Chloride, Vitamin C, Aspirin, Caffeine,

Phenylpropanolamine hydrochloride, Ibuprofen, Pseudoephedrine, Nitroglycerin, and Gemfibrozil.

Brief Summary Text (148):
The granules employed according to the present invention are prepared according to standard granulation procedure, as evidenced by the Examples hereof. When a drug or other active therapeutic agent is to be included in the composition, and it is desired that it be released relatively slowly, it is frequently advantageous to pulverize the drug or other therapeutic agent and to coat the particles thereof prior to formulation into a granule with the other essential ingredients of the granules according to the present invention. Suitable coatings may include, for example, sodiumcarboxymethylcellulose and, if desired, a second coating of the drug or other active ingredient particles may be effected using a further cellulose derivative such as ethylcellulose, also as evidenced according to the Examples hereof. When the particles are formed into granules according to normal granulation procedure, either wet or dry procedure as desired, taking into consideration the ingredients involved, they should be screened to provide granules having a particle size between about 30 and 110 mesh, preferably 50 to 70 mesh, and most preferably about 60 mesh, so that the coating thereof with the necessary exterior coating material will provide particles of suitable dimensions for rapid dispersibility in water or other orally-ingestible liquid. Coating of the granules with the powdered gel-forming fiber, animal or vegetable protein, or starch, which is the final step in the preparation thereof, may be readily effected using a fluid-bed granulator or other apparatus of the type which rapidly and conveniently forms a film over the exterior surfaces of the granules. Of course, such fluid-bed granulator may also be used in the first step, that of coating the drug or other active principle particles, when such are to be included in the composition.

Detailed Description Text (4):
A niacin granulate is produced in a fluid-bed granulator (Glatt Air Techniques, Ramsey, N.J.). The niacin is sprayed with Surelease.TM. (Colorcon, West Point, Pa.), an ethyl cellulose preparation, to a 10% level. The resulting granulate is 90% niacin with the 10% Surelease.TM. coating. The granules are screened to a 60 mesh size, and are blended with the following ingredients in the same fluid-bed granulator;

Detailed Description Text (5):
The foregoing ingredients are blended thoroughly in the fluid-bed granulator with air, and are spray dried with a 10% coating of 225 bloom gelatin dispersed in water, the final percentage of the gelatin coating being between about 2% and 25% by weight, preferably 5% to 10% by weight, and in this particular case about 7.5% by weight of the finished granules. The resulting granules are again screened to a 60 mesh size.

Detailed Description Text (6):
These granules can be mixed in water or other beverage at a dose of 1 teaspoon or 5 grams, to give an extremely effective antihypercholesterolemic dose of the niacin, without the guar fiber gelling up and solidifying. Furthermore, the niacin is not immediately released in the water so that it does not go directly into the bloodstream resulting in the typical niacin side effects of cutaneous flushing, itching, and general irritation. When the instant drink mix reaches the acid environment of the stomach or, when left long enough in solution, the gelatin dissolves, releasing the gel-forming fiber, calcium carbonate, citric acid and niacin through the production of carbon dioxide. The release of niacin is further slowed down by the coating of Surelease.TM., so that there is a second-stage gradual release of the niacin after the fiber has been properly dispersed by the mineral carbonate and the food-grade acid.

Detailed Description Text (16):
The above blend is then spray dried with a coating of guar gum at a 0.5% level

dissolved in water. The resulting granules were screened to 60 mesh and, when stirred in water, dispersed well and did not immediately gel up. The calcium carbonate and citric acid helped to disperse the guar gum once the granules began dissolving, the calcium carbonate by the release of carbon dioxide in the acid environment of the stomach. Other fibers, mineral salts, and acids may obviously replace those employed in the foregoing Example with or without the added presence of a pharmaceutically-active compound such as aspirin, Vitamin C, niacin, or the like, to provide an effective dose of the selected compound for its intended physiological effect.

Detailed Description Text (20):
The foregoing blend is then sprayed with a coating of sodium caseinate at a 10% level, the weight percent of the coating being about 10% of the composition, dried, and blended with orange flavor and aspartame. The granules have locked-in nutrition which is protected from oxidation and light by the sodium caseinate coating. The composition also delivers a dispersed fiber when it dissolves in the stomach. As in the previous Examples, the granules can be mixed in water without immediately dissolving and gelling. When they reach the acid environment of the stomach, the coating dissolves and the nutritional components and fiber are released and dispersed in a gradual manner like food, by the action of the citric acid in combination with the carbon dioxide released by the calcium carbonate.

CLAIMS:

1. A readily-dispersible physiologically-effective drink mix composition which can be made into a drinkable dispersion by admixture with water or another orally-ingestible liquid comprising granules consisting essentially of a blend of a mineral salt which releases a physiologically-acceptable gas upon ingestion, a physiologically-acceptable edible acid, and a gel-forming dietary fiber, said granules being coated with a gel-forming dietary fiber, starch, or protein coating, wherein an orally-ingestible pharmaceutically-active compound is included in said granules.

4. The drink mix of claim 3, wherein said gel-forming dietary fiber coating is also guar gum.

9. The drink mix of claim 8, wherein said coating is a guar-gum coating.

13. The drink mix of claim 1, wherein the coating on the granules comprises about 2% to about 25% by weight of the composition.

14. The drink mix of claim 1, wherein the coating on the granules comprises about 5% to about 10% by weight of the composition.

17. The drink mix of claim 1, wherein the gel-forming dietary fiber comprises about 25% to about 98% by weight of the composition, the physiologically-acceptable acid comprises about 0.5% to about 10% by weight of the composition, the mineral salt comprises about 1% to about 30% by weight of the composition, and the coating comprises about 2% to about 25% by weight of the composition.

18. The drink mix of claim 17, wherein the coating comprises about 5% to about 10% by weight of the composition.

19. The drink mix of claim 1, with a cellulose coating about the granules thereof.

20. The drink mix of claim 2, with a cellulose coating about the granules thereof.

21. The drink mix of claim 19, wherein the coating is a combination of a carboxymethyl cellulose coating and an ethyl cellulose coating.

22. The drink mix of claim 20, wherein the coating is a combination of a carboxymethyl cellulose coating and an ethyl cellulose coating.

27. A readily-dispersible drink mix composition which can be mixed in water or other orally-ingestible liquid and orally ingested, comprising granules consisting essentially of, by weight of the composition:

a gel-forming dietary fiber in amount of about 25% to about 98% by weight of the composition,

a mineral salt which releases a physiologically-acceptable gas upon ingestion, in amount of about 1% to about 30% by weight of the composition,

a pharmacologically-acceptable edible acid in amount of about 0.5% to about 10% by weight of the composition,

said granules being coated externally with a coating selected from the group consisting of a gel-forming fiber, an animal or vegetable protein, and a starch, said coating being present in amount of about 2% to about 25% by weight of the composition, wherein an orally-ingestible biologically-absorbable drug or other active therapeutic agent is present in the granules in amount of about 1% to about 50% by weight of the composition.

28. The composition of claim 27, wherein the external coating is a gel-forming fiber which is the same as the fiber present internally of the granules.

29. The composition of claim 27, wherein the coating is present in amount of about 5% to about 10% by weight of the composition.

34. The method of claim 33, wherein said gel-forming dietary fiber coating is also guar gum.

39. The method of claim 38, wherein said coating is a guar-gum coating.

43. The method of claim 31, wherein the coating on the granules comprises about 2% to about 25% by weight of the composition.

44. The method of claim 31, wherein the coating on the granules comprises about 5% to about 10% by weight of the composition.

47. The method of claim 31, wherein the gel-forming dietary fiber comprises about 25% to about 98% by weight of the composition, the physiologically-acceptable acid comprises about 0.5% to about 10% by weight of the composition, the mineral salt comprises about 1% to about 30% by weight of the composition, and the coating comprises about 2% to about 25% by weight of the composition.

48. The method of claim 47, wherein the coating comprises about 5% to about 10% by weight of the composition.

49. The method of claim 31, wherein the drink mix has a cellulose coating about the granules thereof.

50. The method of claim 32, wherein the drink mix has a cellulose coating about the granules thereof.

51. The method of claim 49, wherein the coating is a combination of a carboxymethyl cellulose coating and an ethyl cellulose coating.

52. The method of claim 50, wherein the coating is a combination of a carboxymethyl cellulose coating and an ethyl cellulose coating.

57. A method for administering a gel-forming dietary fiber and an orally-ingestible pharmaceutically-active compound to a human being, comprising the step of administering the gel-forming dietary fiber and compound to said human being in the form of a fiber drink mix composition which can be mixed in water or other orally-ingestible liquid and orally ingested, the resulting solution being effective in reducing serum cholesterol, comprising granules consisting essentially of, by weight of the composition:

a gel-forming dietary fiber in amount of about 25% to about 98% by weight of the composition,

a mineral salt which releases a physiologically-acceptable gas upon ingestion, in amount of about 1% to about 30% by weight of the composition,

a pharmacologically-acceptable edible acid in amount of about 0.5% to about 10% by weight of the composition,

said granules being coated externally with a coating selected from the group consisting of a gel-forming fiber, an animal or vegetable protein, and a starch, said coating being present in amount of about 2% to about 25% by weight of the composition, wherein an orally-ingestible biologically-=absorbable drug or other active therapeutic agent is present in the granules in amount of about 1% to about 50% by weight of the composition.

58. The method of claim 57, wherein the external coating is a gel-forming fiber which is the same as the fiber present internally of the granules.

59. The method of claim 57, wherein the coating is present in amount of about 5% to about 10% by weight of the composition.

Previous Doc Next Doc Go to Doc#